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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,739	06/08/2001	John Russell Robertson	02332-0020 49409-264826	9829
23370	7590	11/06/2003	EXAMINER	
			YU, MISOOK	
		ART UNIT		PAPER NUMBER
		1642		
DATE MAILED: 11/06/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/857,739	ROBERTSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 01 April 2003.

2a) This action is FINAL.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-4,20-22,30-33,50 and 51 is/are pending in the application.

4a) Of the above claim(s) 20-33,50 and 51 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-4 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of group I corresponding to claims 1-4, species MUC1, in Paper No. 13 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 20-33, 50, and 51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-4, 20-33, 50, and 51 are pending and claims 1-4 are examined as to the extent they are drawn to the elected species of MUC1.

### ***Specification***

The disclosure is objected to because of the following informalities: Fig. 4 has amino acids sequence that requires SEQ ID NO. Adding "SEQ ID NO:1" after "the sequence" in line 1 of Figure 4 legend at page 1o of the specification would obviate this objection. Appropriate correction is required.

### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in United Kingdom on 10 December 1998. It is noted, however, that applicant has not filed a certified copy of the GB9827228.9 application as required by 35 U.S.C. 119(b).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites “substantially asymptomatic for pre-neoplasia or cancer” but it is not clear what the metes and bounds are. For the purpose of this Office action, the Office will assume that the limitation means a benign tumor. However, this treatment does not relieve applicant the burden of responding to this rejection.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over either von Mensdorff-Pouilly et al, Eur J Cancer. 1996 Jul;32A(8):1325-31, or Gourevitch et al, Br J Cancer. 1995 Oct;72(4):934-8 in view of Petrarca et al, Eur J Cancer. 1996 Nov;32A(12):2155-63.

The claims are interpreted as drawn to method using MUC-1 autoantibody for detecting circulating MUC-1 antigen in sera from benign to advanced cancer patients with or without treatment. Either either von Mensdorff-Pouilly et al, Eur J Cancer. 1996

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Jul;32A(8):1325-31, or Gourevitch et al teaches presence of circulating MUC-1 in sera of patients from benign to advanced cancer with various stages is present. Note page 936 and Fig. 2 of Gourevitch et al and Tables 1-6 of von Mensdorff-Pouilly. The presence of circulating MUC-1 in sera of patients from benign to advanced cancer in the two primary references was detected with monoclonal antibody, not MUC-1 autoantibody. The primary references do not teach MUC-1 autoantibody. However, Petrarca et al teach how to prepare MUC-1 autoantibody that meets the definition of "autoantibody" according to the specification at page 3 lines 25-33 "an naturally occurring antibody in that it recognizes the said self-originated antigen but which is produced outside the body, for example, by an immortalized cell". Petrarca et al at page 2161, last two paragraphs also teach that the MUC-1 autoantibody is "capable of successfully binding to ...circulating antigen", indicating that the MUC-1 autoantibody is a functional equivalent of the monoclonal antibody capable of presence of circulating MUC-1 in sera of patients from benign to advanced cancer. When one could not find the monoclonal antibody in the stock freezer but can find the MUC-1 antoantibody, and one has to get the result of whether one has the circulating antigen before the next shipment of the monoclonal antibody arrives, one having ordinary skill in the art at the time the claimed invention would have been motivated to use the MUC-1 autoantibody to detect the circulating MUC-1 antigen with reasonable expectation of success since the secondary reference teaches that the autoantibody is the functional equivalent of capable of detecting the circulating antigen.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*M*  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

Misook Yu  
October 28, 2003